Complete Summary

GUIDELINE TITLE

Frequency of application of topical corticosteroids for atopic eczema.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Frequency of application of topical corticosteroids for atopic eczema. London (UK): National Institute for Clinical Excellence (NICE); 2004 Aug. 34 p. (Technology appraisal guidance; no. 81).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Atopic eczema

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Dermatology
Family Practice

Internal Medicine
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To assess the clinical and cost-effectiveness of once-daily use of topical corticosteroids versus more frequent use of same potency topical corticosteroids in the treatment of people with atopic eczema

TARGET POPULATION

Children and adults with atopic eczema

INTERVENTIONS AND PRACTICES CONSIDERED

Once-daily versus more frequent use of topical corticosteroids

Note: This guideline does not include the use of topical agents that combine corticosteroids with other active agents (for example, antimicrobials or salicylic acid).

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness: Studies were included if they reported one or more of the following as primary outcomes: overall response to treatment (e.g., using severity scores), impact on clinical features of the condition (e.g., erythema, induration, pruritus, excoriation, thickening), relapse/flare-up rate, side-effects, compliance, tolerability, patient preference measures, and quality of life.
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology

considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Southampton Health Technology Assessment Centre (see the "Companion Documents" field).

Search Strategy

Sources of information, search terms, and a flow chart outlining the identification of studies are described in Appendix 3 of the technology assessment (see "Companion Documents" field). The most recent search was performed in October 2003.

Manufacturers' submissions to the National Institute for Health and Clinical Excellence (NICE) were reviewed for additional studies. The full unpublished reports of a study and its subgroup analysis, published as abstracts only, were obtained from GlaxoSmithKline (GSK). The full report of subgroup analysis from the eligible study by Bleehen and colleagues was also obtained from GSK, also previously published as an abstract.

The data from the manufacturers' submissions were not classed as commercial in confidence.

Identification of Trials

Titles and abstracts of studies identified by the search strategy were assessed for potential eligibility by one reviewer and checked by a second reviewer. The full text of relevant papers was then obtained and inclusion criteria applied by two reviewers.

Data were extracted by one reviewer using a standard data extraction form and checked by a second reviewer.

Inclusion Criteria and Exclusion Criteria

Studies comparing once daily versus more frequent application of topical corticosteroids of the same potency were included in the review. Studies comparing corticosteroids with different potencies were excluded. The review included topical corticosteroids reported in section 13.4 of the British National Formulary (BNF), excluding compound preparations (i.e., antimicrobials, preparations containing added ingredients).

The review includes children and adults with atopic eczema (atopic dermatitis). Patients with other types of eczema such as contact dermatitis, seborrhoeic eczema, varicose eczema, and discoid eczema were excluded. Where uncertainty existed over the classification of disease in published studies, a clinical advisor determined the appropriateness of inclusion of the study in the review.

Systematic reviews and meta-analyses of randomised controlled trials (RCTs) as well as individual RCTs were included. The review considers products by potency grouping, and where no RCT evidence was identified for a potency group the inclusion of controlled clinical trials (CCTs) (with concurrent controls) was

considered. Reports published only as abstracts and non-English language studies were excluded.

Outcomes

See "Major Outcomes Considered" field in this summary.

NUMBER OF SOURCE DOCUMENTS

One systematic review and ten randomised controlled trials met the inclusion criteria for the review.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Southampton Health Technology Assessment Centre (see the "Companion Documents" field).

Methods of Analysis

The quality of included systematic reviews was assessed using criteria recommended by National Health Service (NHS) Centre for Reviews and Dissemination (CRD) (Appendix 4 of the technology assessment), and randomised controlled trials (RCTs) were judged in accordance with chapters II.5 of NHS CRD Report 452 (Appendix 5 of the technology assessment). Quality criteria were applied by one reviewer and checked by a second reviewer.

At each stage, any differences in opinion were resolved through discussion or consultation with a third reviewer.

Data Synthesis

Data were synthesised through a narrative review with tabulation of results of all included studies. Full data extraction forms can be seen in Appendix 6 to Appendix

9 in the technology assessment. It was considered inappropriate to combine the studies in a meta-analysis due to clinical heterogeneity (e.g., differences in product and comparators used, differences in patient group, outcomes and method of assessing outcomes, and differences in duration of follow-up), however forest plots using risk ratios (RR) are presented for illustration of the most commonly reported outcomes. Results are based on data from available participants rather than numbers randomised, as it was assumed that study withdrawals and missing data could reasonably be due to either an improvement or worsening of symptoms.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients, and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The Assessment Group did not identify any published economic evaluations that examined frequency of use of same-potency topical corticosteroids. No economic evaluations were identified or submitted by the manufacturers or other consultees. No quality-of-life or patient preference outcomes were included in any of the studies in the systematic review. The Assessment Group concluded that there was no basis to draw firm conclusions over the relative effectiveness of once-daily versus more frequent use of same-potency topical corticosteroids for atopic eczema. Consequently, the economic analysis assumes equivalent effectiveness of once-daily application and more frequent application of topical corticosteroids, and cost-minimisation analysis was undertaken.

See Section 4.2 of the original guideline document for a detailed discussion and more information.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

This appraisal relates to the frequency of application of topical corticosteroids in the treatment of atopic eczema. It does not include the use of topical agents that combine corticosteroids with other active agents (for example, antimicrobials or salicylic acid).

- It is recommended that topical corticosteroids for atopic eczema should be prescribed for application only once or twice daily.
- It is recommended that where more than one alternative topical corticosteroid is considered clinically appropriate within a potency class, the drug with the lowest acquisition cost should be prescribed, taking into account pack size and frequency of application.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of topical corticosteroids for the treatment of atopic eczema

POTENTIAL HARMS

The most widespread side effect of topical corticosteroid treatment is skin atrophy, where the skin becomes thin and may become easily bruised. This is more likely to occur on areas where the skin is already thin, such as the face or flexures. Absorption is greatest in these areas and therefore the use of potent steroids on these sites should generally be avoided. The skin may recover gradually after stopping treatment, but the original structure may never return. Prolonged or excessive use of potent steroids causes the dermis to lose its elasticity and stretch marks (striae) to appear, which are permanent. Children, especially babies, are particularly susceptible to side effects.

For full details of side effects and contraindications, see the Summaries of Product Characteristics, available at http://emc.medicines.org.uk/.

CONTRAINDICATIONS

CONTRAINDICATIONS

The more potent corticosteroids are contraindicated for infants less than 1 year old.

For full details of side effects and contraindications, see the Summaries of Product Characteristics, available at http://emc.medicines.org.uk/.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation and Audit

- All clinicians who care for people with atopic eczema should review their current practice and policies to take account of the guidance set out in Section 1 of the original guideline document (and the "Major Recommendations" field).
- Local guidelines or care pathways for people with atopic eczema should incorporate the guidance.
- To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix C of the original guideline document.
- Topical corticosteroids for atopic eczema are prescribed for application only once or twice daily.
- If more than one alternative topical corticosteroid is considered clinically appropriate within a potency class, the drug with the lowest acquisition cost is prescribed.
- Local clinical audits could also include measurement of compliance with recognised guidelines for the management of atopic eczema and the effectiveness of patient education on the use of topical corticosteroids.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Frequency of application of topical corticosteroids for atopic eczema. London (UK): National Institute for Clinical Excellence (NICE); 2004 Aug. 34 p. (Technology appraisal guidance; no. 81).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Aug

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. 11 Strand, London, WC2N 5HR.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available

- Frequency of application of topical corticosteroids for atopic eczema. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2004 Aug. 2 p. (Technology appraisal 81). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Clinical and cost-effectiveness of once daily versus more frequent use of same potency topical corticosteroids for atopic eczema: a systematic review and

economic evaluation. Assessment report. Southampton (UK): Southampton Health Technology Assessments Centre; 2003 Nov. 142 p. (Technology appraisal 81). Electronic copies: Available in PDF from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Appendix C of the original guideline document.

PATIENT RESOURCES

The following is available:

- How often should corticosteroids be applied for atopic eczema? Understanding NICE guidance - information for people with atopic eczema, their families and carers, and the public. London: National Institute for Health and Clinical Excellence. 2004 Aug. 10 p. Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

NGC STATUS

This NGC summary was completed by ECRI on November 9, 2005.

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